

**FILED UNDER SEAL**

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SEALED PLAINTIFF

v.

SEALED DEFENDANT

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**FILED UNDER SEAL**

**UNITED STATES' NOTICE OF ELECTION  
TO INTERVENE IN PART FOR THE PURPOSES OF SETTLEMENT  
AND TO DECLINE TO INTERVENE IN PART  
AND FOR PARTIAL LIFT OF THE SEAL**

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**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, <u>et al.</u>	:	
<u>ex rel.</u> GERARDO TORRES,	:	
	:	
Plaintiff,	:	CIVIL ACTION NO. 08-cv-4795
	:	
v.	:	
	:	
SHIRE SPECIALTY	:	
PHARMACEUTICALS	:	
	:	
And	:	
	:	
NOVEN PHARMACEUTICALS,	:	
	:	
Defendants.	:	

**UNITED STATES' NOTICE OF ELECTION  
TO INTERVENE IN PART FOR THE PURPOSES OF SETTLEMENT  
AND TO DECLINE TO INTERVENE IN PART**

Pursuant to the False Claims Act, as amended, 31 U.S.C. § 3730(b), the United States of America notifies the Court of its decision to intervene in part of this action and to decline to intervene in part of this action, as set forth herein.

1. On February 14, 2011, Relator Gerardo Torres ("Relator") filed his Fifth Amended Complaint in the above-captioned case against Defendants Shire Specialty Pharmaceuticals, Shire PLC, Shire US, Inc., Shire Pharmaceuticals, Inc., Shire, LLC, Shire Development, Inc., Shire US Manufacturing, Inc. (collectively, the "Shire Defendants") and Noven Pharmaceuticals, Inc.

2. On February 28, 2011, the United States filed a notice with the Court advising that it had not completed its investigation and was therefore unable to decide whether to

intervene in the action at that time. At all times thereafter, the United States continued to take the lead on the investigation of the Relator's allegations.

3. On September 18, 2014, the United States and the Relator entered into a settlement agreement (the "Settlement Agreement") with Shire Pharmaceuticals LLC, acting on behalf of the Shire Defendants, to resolve certain allegations in Relator's Fifth Amended Complaint.<sup>1</sup>

4. In light of the Settlement Agreement between the parties, the United States hereby gives notice that it intervenes in part and declines in part in this Civil Action as follows:

a. The United States hereby intervenes as to the Relator's allegations that, from January 2004 through December 2007, Shire improperly promoted Adderall XR (1) as clinically superior to other attention deficit hyperactivity disorder ("ADHD") drugs based on its mechanism of action and its ability to "normalize" patients; (2) as effective in preventing certain issues linked to ADHD; and (3) for the treatment of conduct disorder, an indication for use which was not approved by the FDA.

b. The United States further intervenes as to the Relator's allegations that, from February 2007 through September 2010, Shire improperly promoted Vyvanse as non-abuseable or less abuseable than other ADHD drugs, and improperly assisted physicians with the prior authorization process for Medicaid prescriptions of Vyvanse.

c. The United States also intervenes as the Relator's allegations that, from April 2006 to September 2010, Shire was aware that the Daytrana patch demonstrated difficulty in sticking to the patient's body and separating from the packaging, causing patients to receive less therapy than the patch was supposed to provide.

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<sup>1</sup> The Settlement Agreement also resolves claims not alleged in the Relator's Fifth Amended Complaint.

d. The United States declines to intervene as to all other allegations against the Shire Defendants set forth in the Fifth Amended Complaint.

e. The United States also declines to intervene in all allegations against Defendant Noven Pharmaceuticals.

5. The Settling States<sup>2</sup>, through Nicholas N. Paul, the Supervising Deputy Attorney General for the Bureau of Medi-Cal Fraud and Elder Abuse, California Attorney General's Office, have authorized the United States to inform the Court that the Settling States also intervene in part and decline in part, in accord with Paragraph 4 above.

6. Under the terms and conditions of the Settlement Agreement the parties, the United States, Relator, and the Settling States will file a Stipulation of Dismissal in this action following the payment of the settlement amount specified in the Settlement Agreement.

7. The United States further requests that the Relator's Fifth Amended Complaint, this Notice, and the attached proposed Order be unsealed. The United States requests that all other papers on file in this action remain under seal because in discussing the content and extent of the United States' investigation, such papers are provided by law to the Court alone for the sole purpose of evaluating whether the seal and time for making an election to intervene should be extended.

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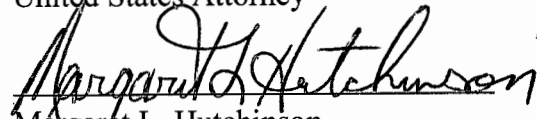
<sup>2</sup> The States that are named in this action and that have signed settlement agreements are: Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Utah, Virginia, Wisconsin, and the District of Columbia.


Respectfully,

THE UNITED STATES

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*On behalf of the State of California and the States  
of Arkansas, Colorado, Connecticut, Delaware,  
Florida, Georgia, Hawaii, Illinois, Indiana,  
Maryland, Massachusetts, Michigan, Minnesota,  
Montana, Nevada, New Hampshire, New Jersey,  
New Mexico, New York, North Carolina, Oklahoma,  
Rhode Island, Tennessee, Texas, Utah, Virginia,  
Wisconsin, and the District of Columbia.*

Dated: September 19, 2014

- UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

3. All papers or Orders filed in this matter after the date of this Order shall be filed without being placed under seal, except as separately ordered by this Court.

BY THE COURT:

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HONORABLE PAUL S. DIAMOND  
United States District Judge



**CERTIFICATE OF SERVICE**

The undersigned attorney certifies that a true and correct copy of the foregoing United States' Notice of Election to Intervene in Part for the Purposes of Settlement and to Decline to Intervene in Part and for Partial Lift of the Seal was served this 19th day of September, 2014 on the following by first class mail, postage prepaid:

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